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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,834	03/16/2004	Steven M. Ruben	PZ029P1D3	2119

22428 7590 05/12/2008
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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,834	RUBEN ET AL.	
	Examiner	Art Unit	
	FOZIA M. HAMUD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/24/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-15 and 17-31* is/are pending in the application.

4a) Of the above claim(s) *1-10,13-15 and 17-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicant's Amendment:

1a. Applicants' amendment filed, on 24 January 2008 has been entered.

Status of Claims

1b. Claims 11-12 and 16 have been cancelled, new claims 27-31 have been added. Thus claims 1-10, 13-15, 17-31 are pending, of which claims 1-10, 13-15 and 17-26 stand withdrawn from consideration as being drawn to non-elected invention. Claims 27-31 are under consideration in the instant application. Claims 27 and 31 recite polypeptide of SEQ ID NO: 347, 348, 349, these sequences will be searched and examined, because these sequences consist amino acid residues 126-137, 99-119, 98-105, (respectively) of SEQ ID NO:161.

Response to Applicant's Argument:

2. The following rejections are withdrawn in light of Applicants' arguments:

All of the rejections of cancelled claims 11-12 and 16 are moot.

New Rejections necessitated by Applicants' Amendment:

Priority:

3. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by PCT/US99/13418, filed on 15 June 1999, because this application discloses the polypeptide of SEQ ID NO:161, as SEQ ID NO:159 and SEQ ID NOs: 347, 348 and 349 as SEQ ID NOs: 338, 339 and 340, respectively, however,

none of the provisional applications disclose said polypeptides. Accordingly, the effective filing of the current application is 15 June 1999.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 06/15/1999, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 06/15/1999.

Claim Rejections - 35 USC § 112, first paragraph:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide having the amino acid sequence set forth in SEQ ID NO:161, does not reasonably provide enablement for an isolated polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:347, 348 or 349, or the fragments of the polypeptide of SEQ ID NO:161 recited in claims 29 and 31, or a polypeptide that differs from the polypeptide of SEQ ID NO:347, 348 or 349 or a polypeptide that differs from the fragments of the polypeptide of SEQ ID NO:161 recited in claim 29 by a single amino acid, wherein said polypeptide is capable of generating or selecting an antibody that binds said polypeptide. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 27 is drawn to an isolated polypeptide that consists the amino acid sequence set forth in SEQ ID NO:347, 348 or 349. It is noted that SEQ ID NO:347 consists amino acid residues 126-137 of SEQ ID NO:161, SEQ ID NO: 348 consists amino acid residues 99-119 of SEQ ID NO:161, and SEQ ID NO:349 consists amino acid residues 98-105 of SEQ ID NO:161, (see page 70, section 0216). Thus claims 27, 29 and 31 encompass fragments of the polypeptide of SEQ ID NO:161. Claims 28 and 30 encompass polypeptides that differ from said fragments by a single amino acid that are capable of generating or selecting antibodies that specifically bind said polypeptides. Although the instant specification discloses that the polypeptide of SEQ ID NO:161 is expressed in ovarian cancer and thus can be used to diagnose said cancer, it does not teach that fragments of said polypeptide can also be used for ovarian cancer diagnosis. Undue experimentation would be required by the skilled artisan to determine a nexus between ovarian cancer and the claimed fragments. Furthermore, one of ordinary skill in the art would not reasonably predict that a fragment that consists 5, 6, 7, 8 or 21 amino acid residues of the polypeptide of SEQ ID NO:161, as encompassed by the instant claims would retain a desired activity or would be expressed in ovarian cancer. The specification does not disclose that the recited fragments are correlated to the functional integrity of the polypeptide of SEQ ID NO:161. Thus, the skilled artisan would not be able how to use the claimed fragments. Claims 28 and 30, recite the limitation, “wherein the recited fragment is capable of generating or

selecting an antibody that specifically binds to the polypeptide", however, since the claimed fragments are not enabled, because the skilled artisan would not know how to use them, an antibody that binds them would not be useful as well. Moreover, one of skill in the art would require additional guidance, such as information as to the significance of the claimed fragments regarding the functional integrity of SEQ ID NO:161. In Ex parte Forman, 230 USPQ 546 (Bd. Pat. Appls, and Interf. 1986), the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. The level of skill in the art of molecular biology is high, but the nature of the invention is not well characterized (i.e. the polypeptide of SEQ ID NO:161 of the instant invention is novel). Therefore, since the state of the prior art is relatively silent to the invention that is claimed, and since Applicants have not provided whether the claimed fragments of the polypeptide are critical for its function, or any disorders that involve said fragments, the skilled artisan would not know how to use the claimed fragments. Accordingly, while the skilled artisan would be able to use the polypeptide of SEQ ID NO:161, said artisan would not be able to use the claimed fragments, since the specification fails to disclose the significance of said fragments. Thus without information regarding whether the claimed fragments are

critical to the functional integrity of the polypeptide of SEQ ID NO:161, the full scope of the claimed invention is not enabled.

Claim rejections-35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27, 28, 29 and 31 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 27, 28, 29 and 31, recite "...a combination of two or more of (a)-(c)..." (for example). However, it is unclear what is encompassed by said limitation. Does this mean that the encompassed polypeptide consists of, for example, Thr41-Gly47 of SEQ ID NO:161 attached to Pro362-Val374, attached to Pro171-Asp176, etc. The specification does not define how said fragments are combined and how many are combined. The metes and bounds of the claims cannot be ascertained.

Conclusion:

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
06 May 2008

/Bridget E Bunner/
Primary Examiner, Art Unit 1647